

### REMARKS

Applicants respectfully request reconsideration of the application identified above. Claims 1-8, 14-22, 24, 25 and 27-29 are currently pending in the application. Only claims 1, 21, 22, 24, 25 and 27 are in independent form. The rejections as conceivably applied to the pending claims are respectfully traversed.

#### I. Indefiniteness Rejections

Claims 1-8, 14-22 and 27-29 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The examiner has indicated that claim 1 lacks clarity in the phrase “slowly implantable” lacks specificity. Claim 1 has been amended to include language that more specifically defines the subject matter of the present invention.

Additionally, the Office Action indicates that the subject matters of claims 15, 16, 17, 18, 19 and 20 are vague and lack antecedent basis. The claims have been amended herewith to provide proper antecedent basis for all terminology used in the rejected claims.

Additionally, the Office Action indicates that the subject matter of claims 15, 16, 17, 18, 19 and 20 are vague and lack antecedent basis. The claims have been amended herewith to provide proper antecedent basis for all terminology used in the rejected claims.

In view of the foregoing, it is respectfully submitted that the subject matter of the amended claims is not indefinite and reconsideration of the rejection is respectfully requested.

A. Anticipation Rejection based on Balat

Claim 1 is rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent 4,258,724 to Balat et al. ("Balat"). Applicants respectfully traverse this rejection as conceivably applied to the pending claims.

It is well settled that anticipation can only be established by a single prior art reference that identically discloses each and every element of the claimed invention. Anticipation is not shown even if the difference between the claims and the prior art reference are insubstantial. Instead, the cited reference must show exactly what is claimed. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990); *Structural Rubber Prod. Co. v Park Rubber Co.*, 749 F.2d 707, 223 U.S.P.Q. 1264 (Fed. Cir. 1984).

The Office Action states that the Balat et al patent discloses the subject matter of claim 1, namely that Balat et al teaches a slowly implantable electrode. However, it is respectfully submitted that Balat et al refers to and discloses an endocavitary cardiac stimulation probe including anchors to maintain the probe in position. In other words, there is disclosure for a probe for insertion of an electrode via an externally insulated flexible conductor into the heart of a patient. The probe includes anchors that maintain the probe in position, which anchors are covered by a biocompatible material to assist in insertion of the probe. Col. 2, Lns. 40-52. The probe itself is not slowly implanted, instead the anchor is slowly released from the biocompatible material. This does not limit the damage that can occur during the implantation process.

The electrode of the presently pending claim incorporates a shape memory polymer that is slowly deployed into the target tissue. The benefit of the slow deployment is that

it greatly diminishes the inflammatory astrocytic scar reaction or other damage that is normally found when electrodes are inserted into tissue. Shape memory polymers are quite diverse from the standard polymers available and currently in use with regard to electrodes. Such use is thus not considered to be within the skill of one in the art to merely modify the polymer currently being used as disclosed is Balat to replace it with a shape memory polymer. Further, the electrode of Balat would not solve the problem with regard to astrocytic scar reaction and instead, would likely cause additional scar damage. There is no disclosure in Balat for the use of a shape memory polymer to form a slowly implantable electrode recited in the presently pending claims for use as recited in the presently pending claim.

In view of the foregoing, it is respectfully submitted that the subject matter of amended claim is not anticipated by Balat et al and reconsideration of the rejection is respectfully requested.

B. Anticipation Rejection based on Mayer

Claims 1, 7 24 and 25 are rejected by U.S. Patent 4,827,940, to Mayer et al ("Mayer"). Applicants respectfully traverse this rejection as conceivably applied to the pending claims.

The Office Action states that Mayer discloses the subject matter of claim 1, namely that Mayer et al teaches a slowly implantable electrode. However, it is respectfully submitted that Mayer discloses an endocavitary cardiac stimulation probe. In other words, there is disclosure for a probe for insertion of an electrode via an externally insulated flexible conductor into the heart of a patient. The probe includes anchors that maintain the probe in

position, which anchors are covered by a biocompatible material. Col. 2, Lns. 49-60. The probe itself is not slowly implanted, instead the anchor is slowly released from the biocompatible material. This does not limit the damage that can occur during the implantation process.

The electrode of the presently pending claim incorporates a shape memory polymer that is slowly deployed into the target tissue. The benefit of the slow deployment is that it greatly diminishes the inflammatory astrocytic scar reaction or other damage that is normally found when electrodes are inserted into tissue. Shape memory polymers are quite diverse from the standard polymers available and currently in use with regard to electrodes. Such use is thus not considered to be within the skill of one in the art to merely modify the polymer currently being used as disclosed is Mayer to replace it with a shape memory polymer. Further, the electrode of Mayer would not solve the problem with regard to astrocytic scar reaction and instead, would likely cause additional scar damage. There is no disclosure in Mayer for the use of a shape memory polymer to form a slowly implantable electrode recited in the presently pending claims for use as recited in the presently pending claim.

In view of the foregoing, it is respectfully submitted that the subject matter of amended claims are not anticipated by Mayer and reconsideration of the rejection is respectfully requested.

C. Anticipation Rejection based on Parker

Claims 1, 3, 4, 7, 8, 22, 24 and 25 are rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent 5,653,742, to Parker et al. ("Parker"). Applicants respectfully traverse this rejection as conceivably applied to the pending claims.

The examiner asserts that Parker discloses an electrode as recited in the presently pending claims. The implant disclosed in Parker is a cochlear assembly that essentially is a cochlear stimulation device that is used to transmit stimulation pulses from the device to implant electrodes. The device can include a shape memory polymer so that the device can fit within the ear canal of the individual. The shape memory polymer is utilized to enable the device be put in straight and when the shape memory polymer is exposed to the heat of the inner ear, the shape memory polymer will reconfigure to the proper orientation that was pre-determined during assembly of the device. While shape memory polymers are utilized to enable doctors to pre-form a device into a specific configuration and then during implantation have the same device be in a different configuration that makes it easier for assembly or insertion into the ear, there is no disclosure that this would be beneficial to create a tissue implantable electrode from this material. A cochlear implant, which is placed within the ear canal is not exposed to the same problems or scenarios disclosed with regard to an implantable electrodes. Namely, there is no adverse reaction that occurs in the ear, whereas when an electrode is implanted into a tissue numerous adverse reactions can take place that can render the electrode non-functional. Additionally, there is no disclosure in Parker for slow deployment of the device, instead the implant is merely implanted and then exposed and utilized within the body almost immediately as there are no detrimental effects from such a use.

In contrast, the electrode of the presently pending claims can be slowly implanted into a person in order to maintain or monitor activity of perform a treatment. The benefit of the electrodes of the presently pending claims is that they are small in size, implanted within the

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body and used to stimulate, monitor, etc. without creating the adverse reactions described above. It is respectfully submitted that Parker does not disclose the electrode disclosed in the presently pending claims.

Additionally, in view of the foregoing, it is respectfully submitted that the subject matter of the amended claims is not anticipated by Parker et al and reconsideration of the claims are respectfully requested.

D. Anticipation Rejection based on Madsen

Claims 1, 3, 4, 7, 8, 14-20, 22, 24 and 25 are rejected by U.S. Patent 6,091,970 to Madsen ("Madsen"). Applicant respectfully traverses this rejection as conceivably applied to the pending claims.

The array disclosed in Madsen pertains to an array that is placed on a cranial surface, not implanted into tissue. Madsen does not disclose an electrode that is capable of being implanted into tissue without causing undue damage. While at Col. 4, Lns. 34-50 there is disclosed numerous bioresorbable materials that can be used to inter-connect the electrode cables, there is no disclosure of the use of a shape memory polymer material. It is unlikely and not common for one of skill in the art to utilize a shape memory polymer in a manner as recited in the presently pending claims without first being taught to do so.

In view of the foregoing, it is respectfully submitted that the subject matter of amended claims are not anticipated by Madsen and reconsideration of the rejection is respectfully requested.

E. Anticipation Rejection based on Mojarradi et al

Claims 1, 2, 8, 14, 16-18, 20, 21 and 27-29 are rejected by U.S. Publication 2004/0006264, to Mojarradi et al ("Mojarradi"). Applicant respectfully traverses this rejection as conceivably applied to the pending claims.

The Office Action makes specific reference Paragraph 19 in the application, which discloses that the electrode or array may be made of an MEMS sensor and that the micro wires that are inserted into this can be inserted into the brain using currently available deep brain stimulation neurosurgeries. There is no disclosure that such an insertion would be slow, as recited in the rejected claims. Additionally, there is no reference to the use of a shape memory polymer for gradually exposing the electrode to the brain, thereby preventing astrocytic formation, as recited in the rejected claims. In fact, the surgical procedures disclosed in Mojarradi incur the astrocytic formation because of the penetration within the brain and the need for the brain to defend itself

In view of the foregoing, it is respectfully submitted that the subject matter of amended claims are not anticipated by Mojarradi and reconsideration of the rejection is respectfully requested.

F. Anticipation Rejection based on He

Claims 1, 2, 8, 14, 16-18, 20, 21 and 27-29 are rejected by U.S. Publication 2005/0021117, to He et al ("He"). Applicant respectfully traverses this rejection as conceivably applied to the pending claims.

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The Office Action makes specific reference to Paragraph 26 in He, which discloses that the electrode or array may be made of an MEMS sensor and that the micro wires that are inserted into this can be inserted into the brain using currently available deep brain stimulation neuro surgeries. There is no disclosure that such an insertion would be slow. Additionally, there is no reference to the use of a shape memory polymer for gradually exposing the electrode to the brain, thereby preventing astrocytic formation. In fact, the surgical procedures disclosed in He incur the astrocytic formation because of the penetration within the brain and the need for the brain to defend itself.

In view of the foregoing, it is respectfully submitted that the subject matter of the amended claims are not anticipated by He and reconsideration of the rejection is respectfully requested.

II. Obviousness Rejection Based on Parker and Madsen in view of Fischell

Claims 5 and 6 are rejected as being unpatentable over US 5,653,742 to Parker et al ("Parker"), U.S. Patent 6,091,979, to Madsen ("Madsen") in view of U.S. Patent 6, 427, 086 to Fischell et al ("Fischell"). Applicant respectfully traverses this rejection as conceivably applied to claims 5 and 6.

It is well settled that obviousness cannot be established by modifying or combining the teachings of the prior art, absent some teaching, suggestion, or incentive supporting the modification or combination. In re Geiger, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Even if the prior art can be modified to obtain the claimed invention, that fact alone does not render the

claims obvious unless the prior art suggests the desirability of the modification. *In re Laskowski*, 10 U.S.P.Q.2d 1397 (Fed. Cir. 1989); *In re Gordon*, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

The determination of obviousness rests on whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *Kahn v. General Motors Corp.*, 135 F.3d 1472, 45 USPQ2d 1608 (Fed. Cir. 1998). In determining obviousness, four factors should be weighed: (1) the scope and content of the prior art, (2) the differences between the art and the claims at issue, (3) the level of ordinary skill in the art and (4) secondary considerations that may be present. Among the factors supporting a finding of non-obviousness are satisfaction of a long-felt need, failure of others to find a solution to the problem at hand, and copying of the invention by others. *Pro-mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 37 USPQ2d 1626 (Fed. Cir. 1996)

In establishing obviousness under Section 103, the Examiner carries the burden of presenting a *prima facie* case, *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), and must show that the references relied on teach or suggest all of the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970). Obviousness may not be established using hindsight or in the view of the teachings or suggestions of the inventor. *Para-Ordnance Manufacturing, Inc. v. SGS Importers International, Inc.*, 73 F.3d 1085, 37 USPQ2d 1237 (Fed. Cir. 1995), *cert. denied* 117 S. Ct. 80 (1996).

M.P.E.P. 2142 states:

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d

1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to suggest the claimed invention.

When determining the differences between the prior art and the claims at issue, it is essential to view the claims at issue as "the invention as a whole" 35 U.S.C. §103. It is legally improper to focus on the obviousness of substitutions and differences between the claimed invention and the prior art rather than on the obviousness of the claimed invention as a whole relative to that prior art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1383, 231 USPQ 81, 93 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Thus, while obviousness may be found by combining references, absent a suggestion to combine the references, such combination is

inappropriate. *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 26 USPQ2d 1018 (Fed. Cir. 1993). It is insufficient that the prior art discloses the component of the claims sought to be patented. A teaching, suggestion or incentive to make the combination is required for a combination of the art to demonstrate obviousness. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). M.P.E.P. 2143.

It is submitted that there is no motivation for modifying the electrodes disclosed in either Parker or Madsen to include the subject matter taught in Fischell to teach the subject matter of the presently pending claims. The Office Action asserts that the primary references lack the inclusion of a therapeutic material in the coating. The addition of such material to a resorbable coating is well known as shown by Fischell at column 35, lines 25-37. The Office Action concludes that it would have been obvious to a skilled artisan to add such material to the coating to the primary references. However, there is no disclosure or suggestion for the inclusion of such materials and none of the cited references actually teach the claimed invention.

The implant disclosed in Parker is a cochlear assembly that essentially is a cochlear stimulation device that is used to transmit stimulation pulses from the device to implant electrodes. The device can include a shape memory polymer so that the device can fit within the ear canal of the individual. The shape memory polymer is utilized to enable the device be put in straight and when the shape memory polymer is exposed to the heat of the inner ear, the shape memory polymer will reconfigure to the proper orientation that was pre-determined during assembly of the device. While shape memory polymers are utilized to enable doctors to pre-

form a device into a specific configuration and then during implantation have the same device be in a different configuration that makes it easier for assembly or insertion into the ear, there is no disclosure that this would be beneficial to create a tissue implantable electrode from this material. A cochlear implant, which is placed within the ear canal is not exposed to the same problems or scenarios disclosed with regard to an implantable electrodes. Namely, there is no adverse reaction that occurs in the ear, whereas when an electrode is implanted into a tissue numerous adverse reactions can take place that can render the electrode non-functional. Additionally, there is no disclosure in Parker for slow deployment of the device, instead the implant is merely implanted and then exposed and utilized within the body almost immediately as there are no detrimental effects from such a use.

In contrast, the electrode of the presently pending claims can be slowly implanted into a person in order to maintain or monitor activity of perform a treatment. The benefit of the electrodes of the presently pending claims is that they are small in size, implanted within the body and used to stimulate, monitor, etc. without creating the adverse reactions described above. It is respectfully submitted that Parker does not disclose or suggest the electrode disclosed in the presently pending claims.

The array disclosed in Madsen pertains to an array that is placed on a cranial surface, not implanted into brain tissue. Madsen does not disclose an electrode that is capable of being implanted into brain tissue without causing undue damage. While at Col. 4, Lns. 34-50 there is disclosed numerous bioresorbable materials that can be used to inter-connect the electrode cables, there is no disclosure of the use of a shape memory polymer material. It is

unlikely and not common for one of skill in the art to utilize a shape memory polymer in a manner as recited in the presently pending claims without first being taught or suggested to do so.

Fischell discloses the use of a therapeutic coating on an exterior surface of an electrode that is placed on top of the brain, not implanted. By placing the electrodes on the brain surface alleviated many problems associated with implantation. However, there is no motivation in either Parker or Madsen for the inclusion of such a coating and there is no teaching or suggestion for the need for such coatings.

As stated, Fischell does not disclose the electrode of the presently pending claims. Therefore, it is respectfully submitted that it cannot be fairly said that there is motivation from modifying either Parker or Madsen to obtain the subject matter of claims 5 and 6. It is respectfully submitted that absent such disclosure, the claims are patentable over the cited prior art references and reconsideration of the rejection is requested.

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IV. Conclusion

In view of the above Amendment and Remarks, Applicants respectfully submit that the present application is in condition for allowance. A notice to that effect is earnestly and respectfully requested. If the Examiner believes that it would be helpful to resolve any outstanding issues, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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